

Docket No.: NHL-NP-45  
Serial No.: 10/816,465  
Customer No.: 00432

**REMARKS**

The Office Action dated September 22, 2006, has been reviewed in detail and the application has been amended in the sincere effort to place the same in condition for allowance. Reconsideration of the application and allowance in its amended form are requested based on the following remarks.

Applicants retain the right to pursue broader claims under 35 U.S.C. §120.

Applicants have provided a unique solution with respect to problems regarding MEANS FOR ELICITING AN IMMUNE RESPONSE AND A METHOD THEREFOR. Applicants' solution is now claimed in a manner that satisfies the requirements of 35 U.S.C. §101, §102, §103, and §112.

**Rejection of Claims 1-5, 7-15, and 17-20 Under 35 U.S.C. §102:**

Claims 1-5, 7-15, and 17-20 were rejected under 35 U.S.C. §102, as being unpatentable over Schirmbeck et al. Claims 1-20 have been canceled herein, without prejudice. New Claims 21-40 will be discussed in view of the present rejection.

Schirmbeck, as best understood, generally discloses a DNA

expression construct. In use, the DNA expression construct is injected into muscle or skin, which leads to the expression of the antigen(s) encoded in the DNA of the expression construct.

Schirmbeck demonstrates the immunological effect of the expression construct but does not disclose a distinct or specific treatment of a specific disease or diseases.

In contrast, Claim 21 recites a "method of vaccinating a living being to protect against infectious diseases caused by intracellular infection germs using a vaccine comprising a DNA expression construct operable in eukaryotic cells" (emphasis added). Claim 21 further recites the step of: "eliciting, with said DNA expression construct of said injected vaccine, a type 1 cellular mediated immune response in the living being against intracellular infection germs that cause infectious diseases." It is respectfully submitted that Schirmbeck does not teach or suggest either of the above limitations.

Also in contrast to Schirmbeck, Claim 29 recites a "vaccine comprising: a type 1-cellular-mediated-immune-response-eliciting vaccine being configured to be intradermally injected into a living being to protect against infectious diseases caused by intracellular infection germs." Again, Schirmbeck does not teach or disclose this

specific limitation.

Finally in contrast to Schirmbeck, Claim 32 recites a "method of vaccinating a living being to protect against infectious diseases caused by intracellular infection germs using a vaccine comprising a DNA expression construct operable in eukaryotic cells" (emphasis added). Claim 32 further recites the step of: "eliciting, with said DNA expression construct of said injected vaccine, a type 1 cellular mediated immune response in the living being against intracellular infection germs that cause infectious diseases." It is respectfully submitted that Schirmbeck does not teach or suggest either of the above limitations.

In addition, it is respectfully submitted that the art of biology, and especially the art of biogenetics, is a very unpredictable art. Schirmbeck only generally describes a DNA expression construct for immunological uses. A method of treatment of or immunization for a specific disease or diseases using such a DNA expression construct, and/or a vaccine containing such a DNA expression construct for immunizing against a specific disease or diseases, would therefore not be obvious in view of the general disclosure of Schirmbeck. The unpredictability of the art to which Schirmbeck and the present

application most closely relate prevents the possibility of such a determination of obviousness.

It is respectfully submitted that Claims 21, 29, and 32 each distinguish over and are not rendered obvious by Schirmbeck. Claims 22-28, 30-31, and 33-40 are also believed to distinguish over Schirmbeck based on their dependence from Claims 21, 29, and 32, respectively, and for the distinguishing limitations recited therein.

In view of the above, reconsideration and withdrawal of the present rejection is respectfully requested.

**Rejection of Claims 1, 7-11, and 17-20 Under 35 U.S.C. §102:**

Claims 1, 7-11, and 17-20 were rejected under 35 U.S.C. §102, as being unpatentable over Wittig et al. (U.S. Patent 6,451,593). Claims 1-20 have been canceled herein, without prejudice. New Claims 21-40 will be discussed in view of the present rejection.

Wittig, as best understood, generally discloses a DNA expression construct. In use, the DNA expression construct is injected into muscle or skin, which leads to the expression of the antigen(s) encoded in the DNA of the expression construct.

In contrast, Claim 21 recites a "method of vaccinating a living

being to protect against infectious diseases caused by intracellular infection germs using a vaccine comprising a DNA expression construct operable in eukaryotic cells" (emphasis added). Claim 21 further recites the step of: "eliciting, with said DNA expression construct of said injected vaccine, a type 1 cellular mediated immune response in the living being against intracellular infection germs that cause infectious diseases." It is respectfully submitted that Wittig does not teach or suggest either of the above limitations.

Also in contrast to Wittig, Claim 29 recites a "vaccine comprising: a type 1-cellular-mediated-immune-response-eliciting vaccine being configured to be intradermally injected into a living being to protect against infectious diseases caused by intracellular infection germs." Again, Wittig does not teach or disclose this specific limitation.

Finally in contrast to Wittig, Claim 32 recites a "method of vaccinating a living being to protect against infectious diseases caused by intracellular infection germs using a vaccine comprising a DNA expression construct operable in eukaryotic cells" (emphasis added). Claim 32 further recites the step of: "eliciting, with said DNA expression construct of said injected vaccine, a type 1 cellular

mediated immune response in the living being against intracellular infection germs that cause infectious diseases." It is respectfully submitted that Wittig does not teach or suggest either of the above limitations.

In addition, it is respectfully submitted that the art of biology, and especially the art of biogenetics, is a very unpredictable art. Wittig only generally describes a DNA expression construct for immunological uses. A method of treatment of or immunization for a specific disease or diseases using such a DNA expression construct, and/or a vaccine containing such a DNA expression construct for immunizing against a specific disease or diseases, would therefore not be obvious in view of the general disclosure of Wittig. The unpredictability of the art to which Wittig and the present application most closely relate prevents the possibility of such a determination of obviousness.

It is respectfully submitted that Claims 21, 29, and 32 each distinguish over and are not rendered obvious by Wittig. Claims 22-28, 30-31, and 33-40 are also believed to distinguish over Wittig based on their dependence from Claims 21, 29, and 32, respectively, and for the distinguishing limitations recited therein.

In view of the above, reconsideration and withdrawal of the present rejection is respectfully requested.

**Rejection of Claims 1-4, 6, 10-14, and 16 Under 35 U.S.C. §103:**

Claims 1-4, 6, 10-14, and 16 were rejected under 35 U.S.C. §103 as being unpatentable over Schirmbeck and Wittig in view of Liu et al. Claims 1-20 have been canceled herein, without prejudice. New Claims 21-40 will be discussed in view of the present rejection.

Liu, as best understood, discloses that the oligomeric peptide sequence YGRKKRRQRRR from the protein transduction domain of HIV TAT protein mediates the transduction of molecules covalently attached to the peptide into cells. The Examiner stated that, in view of the teachings of Wittig, it would have been obvious to the skilled artisan at the time of filing to attach the oligopeptide YGRKKRRQRRR to a MIDGE construct encoding HbsAG instead of the oligopeptide PKKKRKVEDPYC as taught by Schirmbeck. The Examiner further stated that, based on the specific guidance provided by Schirmbeck for attaching an oligopeptide to a MIDGE construct and the specific guidance for synthesizing the oligopeptide YGRKKRRQRRR provided by Liu, the skilled artisan would have had

a reasonable expectation of success in making a MIDGE DNA expression construct encoding HbsAG covalently attached to YGRKKRRQRRR.

MPEP 2143 sets forth the basic requirements for a *prima facie* case of obviousness as follows:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In view of MPEP 2143, it is respectfully submitted that the above combination fails to satisfy all of the requirements. First, as established above with respect to the rejection of the claims under 35 U.S.C. §102, neither Schirmbeck nor Wittig teaches or suggests some of the claim limitations in Claims 21, 29, and 32. Liu also does not teach or suggest those claim limitations. Therefore, the combination of the references does not teach or suggest all the claim limitations as required by MPEP 2143.



Also, the Examiner stated that there would be a reasonable expectation of success, in view of the teachings of Schirmbeck and Liu, in making a MIDGE DNA expression construct encoding HbsAG covalently attached to YGRKKRRQRRR. Again, as stated above, the art of biology and biogenetics is very unpredictable. It is extremely difficult, if not impossible, to have any reasonable expectation of success when combining teachings. It is respectfully submitted that only upon reading the disclosure of the present application would one be motivated to combine the teachings of either Schirmbeck or Wittig or both with the teachings of Liu since there is no reasonable expectation of success in such a combination. Such hindsight analysis is improper according to MPEP 2143, which states that the "teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure" (emphasis added).

In view of the above, it is respectfully submitted that the above combination is improper and therefore fails to render obvious Claims 21, 29, and 32. Claims 22-28, 30-31, and 33-40 are also believed not to be rendered obvious by the combination based on their dependence from Claims 21, 29, and 32, respectively, and for the

distinguishing limitations recited therein.

In view of the above, reconsideration and withdrawal of the present rejection is respectfully requested.

**Rejection of Claims 1-20 Under 35 U.S.C. §101 and §112, Second Paragraph:**

Claims 1-6 and 10-16 were rejected under 35 U.S.C. §101 and §112, second paragraph, because the claimed recitation of use resulted in the claims being improper method claims as they did not set forth any method steps. Claims 1-20 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The specific reasons for these rejections are set forth on pages 6-8 of the outstanding Office Action.

Claims 1-20 have been canceled herein, without prejudice, and Claims 21-40 are newly presented herein. It is respectfully submitted that Claims 21-40 have been drafted in a manner believed to conform to the requirements of 35 U.S.C. §101 and §112, second paragraph.

**Objections to the Specification:**

The Examiner objected to the specification for the reasons set forth on pages 2-4 of the outstanding Office Action. The specification has been amended herein in a manner believed to overcome these objections and comply with the Examiner's requirements.

**Double Patenting:**

Claims 1, 7-11, and 17-20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/816,591. Claims 1, 7-11, and 17-20 have been canceled herein and new Claims 21-40 have been presented herein. It is respectfully submitted that the amendments to the claims have rendered the present rejection moot as the new claims are patentably distinct from the claims of Application No. 10/816,591.

**Priority Documents:**

The Examiner noted on page 2 of the outstanding Office Action that certified copies of the foreign priority documents DE 101 48

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697.9 and DE 101 56 678.6 have not been filed. The certified copies of these documents are being filed by mail under separate letter.

**Petition for Extension of Time under 37 C.F.R. §1.136(a):**

Applicants hereby petition for a one-month extension of time, from December 22, 2006 until January 22, 2007, in which to file the present amendment in the above-cited case. A payment in the amount of \$60.00, representing the one-month extension fee for a small entity, is submitted herewith.

**Art Made of Record:**

The prior art made of record and not applied has been carefully reviewed, and it is submitted that it does not, either taken singly or in any reasonable combination with the other prior art of record, defeat the patentability of the present invention or render the present invention obvious. Further, Applicants are in agreement with the Examiner that the prior art made of record and not applied does not appear to be material to the patentability of the claims currently pending in this application.

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In view of the above, it is respectfully submitted that this application is in condition for allowance, and early action towards that end is respectfully requested.

**Leave to Delay Treatment of Formal Objections Until Allowable**

**Subject Matter is Indicated:**

In accordance with 37 C.F.R. §1.111, it is hereby respectfully requested that any objections or requirements not fully treated and set forth in the outstanding Office action that relate to form and are not necessary to further consideration of the now pending claims, be held in abeyance until allowable subject matter is indicated.

**Summary and Conclusion:**

It is submitted that Applicants have provided a new and unique MEANS FOR ELICITING AN IMMUNE RESPONSE AND A METHOD THEREFOR. It is submitted that the claims presented herein are fully distinguishable from the prior art. Therefore, it is requested that a Notice of Allowance be issued at an early date.

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Respectfully submitted,

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